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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,759	09/19/2005	Ignacio Blanco Blanco	034284-003	6945

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BUCHANAN, INGERSOLL & ROONEY PC  
POST OFFICE BOX 1404  
ALEXANDRIA, VA 22313-1404

EXAMINER

KOSSON, ROSANNE

ART UNIT PAPER NUMBER

1652

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/549,759

**Applicant(s)**

BLANCO, IGNACIO BLANCO

**Examiner**

Rosanne Kosson

**Art Unit**

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 6-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

The amendment filed on November 22, 2006 has been received and entered. Claims 6-16 have been amended. No claims have been canceled or added. Accordingly, claims 6-16 are examined on the merits herewith.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Priority***

Receipt of an English translation of Applicant's Spanish Application No. 200402282, filed on September 24, 2004, is hereby acknowledged.

#### ***Claim Rejections - 35 USC § 112, second paragraph***

In view of Applicant's amendments to the claims, these rejections are withdrawn.

#### ***Claim Rejections - 35 USC § 102***

Claims 6-16 are rejected again under 35 U.S.C. 102(b) based upon a public use or sale of the invention. This rejection was discussed in the previous Office action.

Applicant asserts that filing an English translation of his Spanish priority document overcomes the rejection, but Applicant has not responded to this rejection. He has responded to the rejection below. This rejection is not that the Journal of Rheumatology publication itself anticipates the claims (i.e., work that was done after the priority date). The rejection is that this article discloses public studies that began in 1992, studies of two sisters. To reiterate, the two sisters regularly saw a number of doctors and were part of a family study of subjects with AAT

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deficiency that began in 1984. The treatment of fibromyalgia with AAT has been public knowledge since 1992, information known at least to the family, their doctors, the people with whom the doctors communicated, and those involved with the Spanish AAT Deficiency Registry and the Alpha1 International Registry (AIR) (see pp. 2082 and 2084, Case Reports). AIR is a multinational research organization of 20 countries, including the U.S. Detailed clinical information on AAT deficiency research is sent to a database in Malmö, Sweden, where it is made accessible to researchers in other countries, including the United States (see Alpha One International Registry (AIR) homepage, <http://www.aatregistry.org/>, printed on August 18, 2006). Because the patients in these case studies have been members of AIR since the late 1990's, the treatment methods in the case studies were known to doctors in the U.S. more than one year before the filing date of the instant invention.

The AAT was administered intravenously on a weekly basis, as recited in the claims, and the amount administered increased the serum level of AAT to an amount about 8-fold higher than the basal level after 24 hours (see claim 13) and to an amount about 100% over basal level after 7 days (see claims 8-9). Although the dose in mg AAT/kg body weight is not indicated in the article, the amount given appears to be the same as in the instant application as the same result is achieved. It is not clear, though, if Blanco et al. are reporting their own work or that of others, in connection with the work of Blanco et al.'s genetic studies on AAT deficiency.

An issue of public use or on sale activity has been raised in this application (see MPEP 2133.02 and 2133.03(II)(b)), and Applicant has not responded to this rejection. In order for the examiner to properly consider patentability of the claimed invention under 35 U.S.C. 102(b), additional information regarding this issue is required as follows. Applicant is requested to provide information specifying the doses and dosing schedules of AAT administered to the two

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sisters and the results obtained. Applicant is also requested to indicate who knew about these case studies, that is, the extent to which these case studies were discussed and published, when and where. If Applicant is aware of any other relevant prior art, in particular, earlier publications of this work, Applicant is required to submit this information in an IDS (see MPEP 2001 and 37 CFR 1.56).

Applicant is reminded that failure to fully reply to this requirement for information will result in a holding of abandonment.

In view of the foregoing, the rejection of record is maintained.

***Claim Rejections - 35 USC § 102/103***

As previously discussed, this rejection pertains to Blanco et al. ("Alpha1-antitrypsin replacement therapy controls fibromyalgia symptoms in 2 patients with PI ZZ alpha1-antitrypsin deficiency," J Rheumatology 31(10):2082-2085, October 2004) as prior art. Because Applicant has filed an English translation of his priority document, this article is considered not to be prior art, and the rejection is withdrawn.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

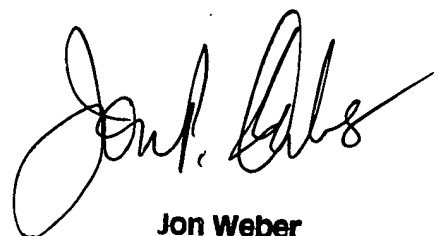
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rosanne Kosson  
Examiner, Art Unit 1652

rk/2006-12-06



**Jon Weber**  
**Supervisory Patent Examiner**